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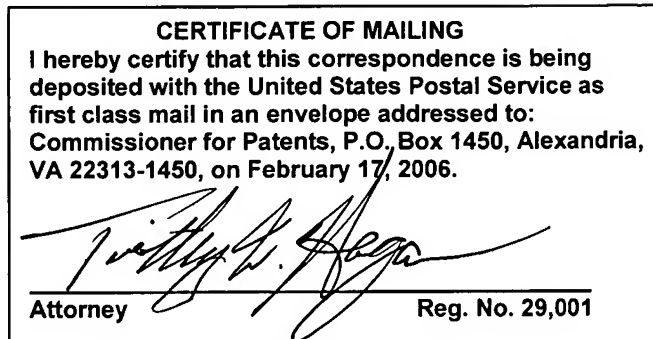
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of

Applicants : William A. Cuevas and Manoj Kumar
Serial No : 10/800,179
Filed : March, 12, 2004
Title : **USE OF REPEAT SEQUENCE PROTEIN POLYMERS
IN PERSONAL CARE COMPOSITIONS**
Docket : DOC0057PA/DC5074/GC792-4
Examiner : A. Kosar
Art Unit : 1654
Conf. No : 8989

MAIL STOP: APPEAL BRIEF - PATENTS
COMMISSIONER FOR PATENTS
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Sir:



BRIEF ON APPEAL

This is an appeal from the Office Action mailed July 21, 2005, finally rejecting claims 1-4, 8-9, 12-14, and 31. A Notice of Appeal was timely mailed on November 21, 2005, with the accompanying fee. Our check in the amount of \$500.00 accompanies this Brief in accordance with 37 CFR §41.20(b)(2). A separate Request for a one-month extension of time in which to file this brief accompanies this paper.

Real Party in Interest

The real party in interest in this application is Genencor International, Inc., by an assignment from the named inventors which is recorded in the files of the U.S. Patent and Trademark Office at Reel 015241, Frame 0572, on October 12, 2004.

Related Appeals and Interferences

Applicants know of no other related appeal or interference that will directly or indirectly affect or have a bearing on the outcome of this appeal.

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Status of Claims

Claims 1-33 are pending in this application. Claims 1-4, 8-9, 12-14, and 31 stand finally rejected and are before this Board for consideration on appeal. Claim 15 has been objected to. Claims 5-7, 10-11, 16-30, 32, and 33 have been withdrawn from consideration pursuant to an election/restriction requirement. A copy of the appealed claims is found in the Appendix attached to this brief.

Status of Amendments

All of the amendments previously filed in this application have been entered. A Request for Reconsideration of the Finality of the Rejection and an Amendment was filed on October 18, 2005. In an Advisory Action mailed November 1, 2005, the Examiner stated that the Request had been considered but the finality of the rejection was maintained. Further, the Request did not place the application in condition for allowance. All grounds of rejection were maintained. An amendment to the specification not affecting this appeal was entered.

Summary of the Claimed Subject Matter

Applicants' invention, as claimed herein, is directed to a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient, wherein the repeat sequence protein polymer formula comprises:

$$T_y[(A_n)_x(B)_b(A'_n)_{x'}(B')_{b'}(A''_n)_{x''}]_i T'_{y'},$$

and wherein: T and T' each comprise an amino acid sequence of from about 1 to about 100 amino acids, wherein the amino acid sequence of T' is the same as or different from the amino acid sequence of T; y and y' are each an integer from 0 to 1, wherein the integer of y' is the same as or different from the integer of y; A, A' and A'' are each individual repeating sequence units comprising from about 3 to about 30 amino acids, wherein the amino acid sequence of A' and the amino acid sequence of A'' are the same as or different from the amino acid sequence of A; n, n',

and n'' are integers of at least 2 and not more than 250; x , x' and x'' are each 0 or an integer of at least 1, wherein each integer varies to provide for at least 30 amino acids in the A' , A' and A'' individual repeating sequence units, and wherein the integer of x' and the integer of x'' are the same as or different from the integer of x ; B and B' each comprise an amino acid sequence of from about 4 to about 50 amino acids, wherein the amino sequence of B' is the same as or different from the amino acid sequence of B ; b and b' are each an integer from 0 to 3, wherein the integer of b' is the same as or different from the integer of b ; i is an integer from 1 to 100, and wherein the personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.

The repeat sequence protein polymers as set forth in claim 1 can include several different amino acid sequences T , T' , A , A' , A'' , B , and B' . The amino acid sequences A , A' , and A'' must comprise repeating sequence units of from about 3 to about 30 amino acids, and the sequences of A , A' , and A'' can be the same or different. Thus, in its simplest form, where y , y' , b , and b' are zero and i is 1, the formula reduces to: $(A_n)_x(A'_{n'})_{x'}(A''_{n'')_{x''}}$. The "wherein" clause defining the A , A' , and A'' amino acid sequences also limits and further defines acceptable values for x , x' , and x'' .

The "wherein" clause directed to defining the x category of enumeratives is as follows: " x , x' and x'' are each 0 or an integer of at least 1, *wherein each integer varies to provide for at least 30 amino acids in the A , A' and A'' individual repeating sequence units*, and wherein the integer of x and the integer of x'' are the same as or different from the integer of x ." Semicolons at the beginning and end of this clause set it off as integral. Prior in the formula, A , A' and A'' are defined as individual repeating sequence units comprising "from about 3 to about 30 amino acids," while n , n' and n'' are the sub-enumeratives of A , A' and A'' respectively, and are integers of at least 2 and not more than 250. Hence, up to the point of categorically defining A_n , a minimum peptide of 6 amino acids results. As previously noted, x , x' and x'' are defined as the sub-enumeratives of (A_n) , $(A'_{n'})$ and (A''_{n'') , respectively. Because the additional recitation that the integers selected for x must vary to provide for at least 30 amino acids in the A , A' and A'' , individual repeating sequence units prevents each of x , x' , and x'' from being zero at the same time.

Thus, at least one of x, x' or x'' cannot be 0 to provide for the requisite at least 30 amino acids in the A, A' and A'' individual repeating units.¹ Applicants believe that it is clear that the minimum peptide length described by the formula recited in claim 1 is 30 amino acids, which is the result if y, y', b and b' are all 0, and x, x' and x'' are varied to yield the requisite 30 amino acid minimum.

At pages 3-4 of the specification, in paragraphs [0014] through [0017], applicants have provided descriptions and definitions for certain terminology found in the specification and claimed subject matter. Thus, "repeat sequence protein polymer" (RSPP) refers to a polymer comprising repeating amino acid sequence units, which repeating units are derived from a natural or synthetic protein. For example, the repeating sequence units may be derived from natural structure supporting materials such as silk, elastin, and collagen. Alternatively, the repeating sequence units may be derived from synthetic structures. "Personal care composition" refers to a product for application to the skin, hair, nails, oral cavity and related membranes for the purposes of improving, cleaning, beautifying, therapeutically treating, caring for these surfaces and membranes.

"An effective amount" refers to the amount of repeat sequence protein polymer which is added to a personal care composition to provide the composition with a desired characteristic or characteristics. "Dispersed phase" is a term well-known to one skilled in the art of emulsion technology, which means that the phase exists as small particles or droplets that are suspended in and surrounded by a continuous phase. The dispersed phase is also known as the internal or discontinuous phase.

Specific example of suitable RSPP's are provided, for example, at pages 4-5 in paragraphs [0019] through [0020]. Methods of making the RSPP's are described at pages 6-7, in paragraphs [0021] through [00222]. The personal care compositions may contain additional components as described, for example, at pages 11-28, in paragraphs [0036] through [0082]. Specific examples of the personal care compositions are provided in Example 15.

¹ Dependent claim 3 explicitly recites this feature of the invention.

Grounds of Rejection to be Reviewed on Appeal

The Examiner stated only a single ground in the final rejection:
Claims 1-4, 8, 9, 12-14, and 31 stand rejected under 35 USC §102(b) as anticipated by Wolfinbarger (US 2002/0147154) in view of Voet (Biochemistry, 2d ed.). Applicants request review of this ground of rejection.

Argument

The Rejection of claims 1-4, 8, 9, 12-14, and 31 under 35 USC §102

Because there is only a single ground of rejection for review, and because claim 1 is the sole independent claim under review, for purposes of this appeal, applicants will argue the patentability of claim 1 as representative of the claims on appeal. The patentability of dependent claim 3 will be separately argued only to the extent that the Examiner directly challenges the scope of the repeat sequence protein polymer formula recited in claim 1.

Claims 1-4, 8, 9, 12-14, and 31 were rejected under 35 USC §102(b) as being anticipated by published U.S. Patent Application 2002/0147154 to Wolfinbarger, J.R., in view of Voet, D. and Voet, J.G. Biochemistry, 2nd Ed. (1995).² The Examiner asserted in the final rejection that Voet taught that collagen comprises the specific sequence:

GL- [HGPIGHHGPRGRTGD(AGP)2(HGP)4]-P,

referring to page 158, Fig. 7-30, which the Examiner asserted to be encompassed by the repeat sequence protein polymer formula recited in claim 1. The Examiner further asserted that Wolfinbarger teaches a cosmetic composition comprising marine invertebrate type V telopeptide

² Applicants note that the Examiner atypically asserted a combination of references in the rejection under §102. In order for this to be proper, the Examiner must be using the second reference merely to define or enable the relevant disclosure of the first reference. "The Federal Circuit regards it as hornbook law that anticipation must be found in a single reference, device or process." Harmon, R.L. *Patents and the Federal Circuit*, 5th Ed. (2001), page 91, citing, *Studiengesellschaft Kohle v. Dart Indus., Inc.*, 726 F.2d 724, 220 USPQ 841 (Fed. Cir. 1984). Additional references may only be used if the purpose of the second reference is "to shed light on what it [the allegedly anticipating reference] would have meant to those skilled in the art at the time." *Id.*

containing collagen in particularly disclosed weight percentages. The implication from the Examiner's statements is that he is asserting that the marine invertebrate type V telopeptide of Wolfinbarger has the same structure as the page 158, Fig. 7-30 bovine $\alpha 1(I)$ collagen described by Voet. Applicants submit that the Examiner has failed to establish that the Voet collagen and the Wolfinbarger telopeptide are the same. Further, the Examiner has failed to establish that either the Voet collagen or the marine invertebrate telopeptide of Wolfinbarger inherently have structures that come within the scope of the formula recited in claim 1.

Anticipation under 35 USC §102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration. *Alco Standard Corp. v. TVA*, 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). The corollary of the rule is that absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 USPQ 81 (Fed. Cir. 1986). Applicants submit that upon close review, Wolfinbarger fails to teach or suggest a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient wherein the repeat sequence protein polymer anticipates the formula recited in claim 1. The second reference, Voet, asserted to structurally define the telopeptide of Wolfinbarger, actually defines a different collagen which also fails to anticipate the formula recited in claim 1.

Claim 1 is directed to a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient. The repeat sequence protein polymer formula comprises: $T_y[(A_n)_x(B)_b(A'_n)_{x'}(B'')_{b'}(A''_n)_{x''}]_i T'_{y'}$ wherein: T and T' each comprise an amino acid sequence of from about 1 to about 100 amino acids, wherein the amino acid sequence of T' is the same as or different from the amino acid sequence of T; y and y' are each an integer from 0 to 1, wherein the integer of y' is the same as or different from the integer of y; A, A' and A'' are each individual repeating sequence units comprising from about 3 to about 30 amino acids, wherein the amino acid sequence of A' and the amino acid sequence of A'' are the same as or different from the amino acid sequence of A; n, n', and n'' are integers of at least 2 and not more than 250; x, x' and x'' are each 0 or an integer of at least 1, wherein each integer varies to provide for at least 30 amino acids in the A, A' and A'' individual repeating sequence units, and wherein the integer of x' and the integer of x'' are the same as or different from the integer of x; B and B' each comprise an amino acid sequence of

from about 4 to about 50 amino acids, wherein the amino sequence of B' is the same as or different from the amino acid sequence of B; b and b' are each an integer from 0 to 3, wherein the integer of b' is the same as or different from the integer of b; i is an integer from 1 to 100. The personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.

The Examiner has failed to prove that the Voet collagen defines the Wolfinbarger telopeptide

In order to establish a prima facie case of anticipation for the Examiner's unusual two-reference §102 rejection, he must prove that Voet, the second reference, (1) is not being used to show elements of the claimed invention³ and (2) establishes that those persons skilled in this art would understand that a claimed feature not explicitly disclosed by the primary reference, would nevertheless be recognized by those persons skilled in the art as necessarily present in the primary reference.⁴ Applicants submit that the Examiner has not carried his evidentiary burden.

In the first place, an unstated assumption which has been made by the Examiner is that all collagens have the same structure, i.e., that the structure of a type V telopeptide from an invertebrate marine animal (Wolfinbarger) has the same structure as bovine $\alpha 1(I)$ collagen (Voet). However, the Voet reference itself states that, "Mammals have at least 30 genetically distinct polypeptide chains comprising 16 collagen variants that occur in different tissues of the same individual." See, page 156. Voet further enumerates multiple different types of collagens (page 159), but does not indicate whether collagens found in mammals versus invertebrate marine life have the same or very similar structures.

³ See, *Studiengesellschaft Kohle, supra*.

⁴ See, *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328, 58 USPQ2d 1545 (Fed. Cir. 2001) ("recourse to extrinsic evidence is proper to determine whether a feature, while not explicitly disclosed, is necessarily present in a reference").

The Examiner has failed to prove that either the Voet collagen or the Wolfinbarger telopeptide meet the recited repeat sequence protein polymer formula recited in the claims.

Further, as previously discussed, the minimum peptide length described by the formula recited in claim 1 is 30 amino acids, which is the result if y, y', b and b' are all 0, and x, x' and x'' are varied to yield the requisite 30 amino acid minimum. Dependent claim 3 explicitly recites that x, x', and x'' cannot all be zero. Applicants submit that the Examiner has misconstrued the formula recited in claim 1 which defines the repeat protein polymers encompassed by that claim. Upon review, the peptide sequence relied upon by the Examiner in Voet does not anticipate the recited formula. The Examiner did correctly identify the peptide sequence of Voet illustrated in Fig. 7-30 on page 158, once re-coded into the single amino acid designator convention, as disclosing the following:

...GL [HGPIGHHGPRGRTGD(AGP)2(HGP)4]-P...

The Examiner then asserted that all the amino acids through GL in the formula above corresponded to the amino acid sequence recited in claim 1 as T. The Examiner further asserted that all of the amino acids in Voet from P through some indeterminate amino acid at the end of the sequence corresponded to the amino acid sequence recited in claim 1 as T'. In both instances, the Examiner assumed that y and y' were each equal to 1, as permitted by the recited formula in claim 1.

Up to this point in the Examiner's analysis, Applicants (with reservations regarding the Examiner's interpretation as to the permissible lengths of T and T'), substantially agree. However, in contravention to the formula, the Examiner then asserted that the intervening 15 amino acid sequence HGPIGHHGPRGRTGD in Voet's formula corresponded to the repeating sequence unit A_n in claim 1. However, that formula specifies that A is a "repeating sequence unit" having a length of from about 3 to about 30 amino acids, with n indicating the number of times that each unit repeats, with n being at least 2 (and thus defining a minimum of two repeating units).

Here, there is no repeating unit in the Voet peptide sequence HGPIGHHGPRGRTGD that could be "A," repeating at least twice. While A is permitted, as recited in the formula in claim 1, to be a 15-residue long peptide sequence, it still must repeat *at least twice*, because "n"

must be at least 2. The sequence identified as A by the Examiner is merely 15 amino acids that do not contain any sequence that repeats at least twice.

Even assuming that the Examiner simply adds this 15-residue sequence to T, thereby making A=AGP, n=2 and A'=HGP, n=4, Applicants submit that the Voet sequence still does not anticipate the formula recited in claim 1. This manipulation of Voet's formula yields an 18-residue sequence that does not meet the requisite claim limitation "wherein each integer varies to provide for *at least 30* amino acids in the A, A' and A" individual repeating sequence units...". Therefore, even if one were to assume that the structures of the marine invertebrate type V telopeptide of Wolfinbarger and the bovine $\alpha 1(I)$ collagen of Voet had the same or very similar amino acid sequences (which applicants submit the Examiner has failed to demonstrate by evidence in this record), Voet's collagen does not comprise a repeat sequence protein polymer as recited in applicants' claims. Accordingly, Wolfinbarger fails to disclose any repeat sequence protein polymers that would anticipate the formula recited in the appealed claims.

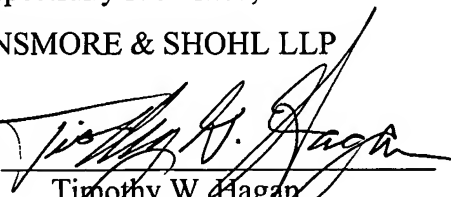
Conclusion

For all of the above reasons, applicants submit that the Examiner has failed to establish a prima facie case of anticipation as to any of the appealed claims. Applicants respectfully request this Board to reverse the rejection in its entirety.

Respectfully submitted,

DINSMORE & SHOHL LLP

By

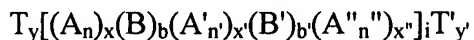


Timothy W. Hagan
Registration No. 29,001

One Dayton Centre
One South Main Street, Suite 1300
Dayton, Ohio 45402-2023
(937) 449-6400
Facsimile: (937) 449-6405
E-mail: tim.hagan@dinslaw.com
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CLAIMS APPENDIX

1. A personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient, wherein the repeat sequence protein polymer formula comprises:



wherein:

T and T' each comprise an amino acid sequence of from about 1 to about 100 amino acids, wherein the amino acid sequence of T' is the same as or different from the amino acid sequence of T;

y and y' are each an integer from 0 to 1, wherein the integer of y' is the same as or different from the integer of y;

A, A' and A'' are each individual repeating sequence units comprising from about 3 to about 30 amino acids, wherein the amino acid sequence of A' and the amino acid sequence of A'' are the same as or different from the amino acid sequence of A;

n, n', and n'' are integers of at least 2 and not more than 250;

x, x' and x'' are each 0 or an integer of at least 1, wherein each integer varies to provide for at least 30 amino acids in the A', A' and A'' individual repeating sequence units, and wherein the integer of x' and the integer of x'' are the same as or different from the integer of x;

B and B' each comprise an amino acid sequence of from about 4 to about 50 amino acids, wherein the amino sequence of B' is the same as or different from the amino acid sequence of B;

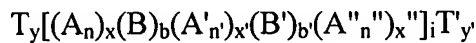
b and b' are each an integer from 0 to 3, wherein the integer of b' is the same as or different from the integer of b;

i is an integer from 1 to 100, and

wherein the personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.

2. The composition of claim 1, wherein the repeat sequence protein polymer comprises a repeating amino acid sequence unit derived from elastin, collagen, abductin, byssus, flagelliform silk, dragline silk, gluten high molecular weight subunit, titin, fibronectin, leminin, gliadin, glue polypeptide, ice nucleating protein, keratin, mucin, RNA polymerase II, resalin or a mixture thereof.

3. The composition of claim 1, wherein the repeat sequence protein polymer formula comprises:



wherein:

T and T' each comprise an amino acid sequence of from about 1 to about 100 amino acids, wherein the amino acid sequence of T' is the same as or different from the amino acid sequence of T;

y and y' are each an integer from 0 to 1, wherein the integer of y' is the same as or different from the integer of y;

A, A' and A'' are each individual repeating sequence units comprising from about 3 to about 30 amino acids, wherein the amino acid sequence of A' and the amino acid sequence of A'' are the same as or different from the amino acid sequence of A;

n, n', and n'' are integers of at least 2 and not more than 250;

x, x' and x'' are each 0 or an integer of at least 1, wherein each integer varies to provide for at least 30 amino acids in the A', A' and A'' individual repeating sequence units, and wherein the integer of x' and the integer of x'' are the same as or different from the integer of x and further wherein x, x' and x'' cannot all be equal to 0;

B and B' each comprise an amino acid sequence of from about 4 to about 50 amino acids, wherein the amino sequence of B' is the same as or different from the amino acid sequence of B;

b and b' are each an integer from 0 to 3, wherein the integer of b' is the same as or different from the integer of b;

i is an integer from 1 to 100.

4. The composition of claim 1, wherein T and T' comprise an amino acid sequence from about 1 to about 60 amino acids

8. The composition of claim 1, wherein i is an integer from 1 to 50.

9. The composition of claim 1, wherein i is an integer from 1 to about 30.

12. The composition of claim 1, wherein the repeat sequence protein polymer comprises from about 0.001 weight % to about 10 weight % of the composition.

13. The composition of claim 1, wherein the repeat sequence protein polymer comprises from about 0.01 weight % to about 5 weight % of the composition.

14. The composition of claim 1, wherein the repeat sequence protein polymer comprises from about 0.01 weight % to about 1 weight % of the composition.

31. The personal care composition as recited in claim 1, further comprising one or more compounds from the group of carriers, excipients, liposomes, active ingredients, biological or botanical products, humectants, emollients, surfactants, thickening agents, silicone components, organic sunscreens, preservatives, neutralizing agents, perfumes or pigments.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.